

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF

Art Unit: 1625

Dugan, Margaret Han

Examiner: Aulakh, Charanjit

INTERNATIONAL APPLICATION NO:

Conf. No.: 7027

PCT/EP03/06848

FILED: June 27, 2003

U.S. APPLICATION NO: 10/518989

35 USC §371 DATE: July 21, 2005

FOR: Combination Comprising a Vasculostatic Compound and an
Alkylating Agent for the Treatment of a Tumor

MS: Issue Fee

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT-PRE-GRANT

Sir:

In accordance with 37 C.F.R. § 1.705(b), Applicant hereby applies for patent term adjustment under 35 U.S.C. § 154(b) of at least 1155 days. This application is being filed before or with payment of the issue fee, as required by 37 C.F.R. § 1.705 (b).

I. Fee

As required by 37 C.F.R. § 1.705(b)(1), please charge Deposit Account No. 19-0314 for \$ 200.00 to cover the required fee (as defined in 37 C.F.R. § 1.18(e)). Please charge any deficiencies or any additional fees due in response to this request to Deposit Account 19-0314.

II. Statement of the Facts Involved

A. Correct Patent Term Adjustment

The Determination of Patent Term Adjustment was received by Applicant on July 24, 2009, indicating a patent term adjustment of 482 days.

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Patentee has calculated a patent term adjustment of at least 1155 days (depending on the issue date) under the Wyeth v. Dudas decision based on the following facts:

Case Law

In *Wyeth v. Dudas*, 2008 U.S. Dist. LEXIS 76063 (D.D.C. 2008), the District Court of the District of Columbia, addressed the United States Patent and Trademark Office (USPTO) interpretation of 35 U.S.C. § 154(b)(2). The Court granted summary judgment in favor of Wyeth, determining that the USPTO misconstrued the first sentence of 35 U.S.C. § 154(b)(2)(A), and as a result, improperly denied Wyeth a portion of patent term to which Wyeth was entitled under 35 U.S.C. § 154.

In the opinion, the Court stated that "the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for 'A delay' or for 'B delay,' whichever is larger, but never A + B." However, Plaintiff Wyeth argued that the § 154(b)(1)(A) and § 154(b)(1)(B) period overlap only if they occur on the same calendar day or days. The Court determined that Wyeth's construction of § 154(b)(2)(B) was correct.

Simply put, the holding of the Court is that the excluded overlap recited in the first sentence of 35 U.S.C. § 154(b)(2)(A) only occurs if a 35 U.S.C. § 154(b)(2)(A) period and a 35 U.S.C. § 154(b)(2)(B) period run concurrently. As such, a patent holder is entitled to recoup the 35 U.S.C. § 154(b)(2)(A) period that falls outside of the 35 U.S.C. § 154(b)(2)(B) period in addition to the 35 U.S.C. § 154(b)(2)(B) period itself.

Relevant Dates

The above-identified patent application has an actual filing date of December 21, 2004.

The above-identified application has a 35 U.S.C. §371 filing date of July 21, 2005.

The first Office Action, which was a Restriction Requirement, was mailed on April 14, 2008, resulting in a PTO delay of 571 days beyond the 14 months provided by 35 U.S.C. §154(b).

A Response to Restriction was received from Applicants by the PTO on May 13, 2008.

A Non-final Rejection was mailed May 28, 2008, resulting in a PTO delay of 0 days.

A Response was received from Applicants by the PTO on November 25, 2008, resulting in an applicant delay of 89 days.

A Final Rejection was mailed February 26, 2009, resulting in a PTO delay of 0 days.

A Response was received from Applicants by the PTO on May 26, 2009, resulting in an applicant delay of 0 days.

A Notice of Allowance was mailed by the PTO on July 24, 2009, resulting in a PTO delay of 0 days.

Accordingly, the total PTO adjustment based on delay under 35 U.S.C. § 154(b)(1)(A) is 571 days. This is in agreement with the PTA History found on Public PAIR.

However, this application is also entitled to a PTA under 35 U.S.C. §154(b)(1)(B) because it has been pending for more than three years from its actual filing date. The 35 U.S.C. §154(b)(1)(B) period for the above-identified application began on December 21, 2007 (three years after the actual filing date of December 21, 2004) and will end upon issuance of a patent. Accordingly, as of October 24, 2009, the 35 U.S.C. § 154(b)(1)(B) period is 673 days, which will continue to increase until a patent issues.

Within the 35 U.S.C. § 154(b)(1)(B) period (i.e., from December 21, 2007 to patent issuance), there are currently no overlapping delays that should be excluded from the patent term adjustment calculation under the holding of *Wyeth v. Dudas*.

Accordingly, the current sum of the 35 U.S.C. § 154(b)(1)(B) and non-overlapping 35 U.S.C. § 154(b)(1)(A) delay is $(571 \text{ days} + 673 \text{ days}) = 1244 \text{ days}$.

Under 35 U.S.C. § 154(b)(2)(C), the total period of PTO delay is reduced by the period of applicant delay, which is 89 days.

Accordingly, the correct patent term adjustment as of October 24, 2009 for the above identified application is 1155 days (the difference between the total period of PTO delay under 35 U.S.C. § 154(b)(1) and applicant delay under 35 U.S.C. § 154(b)(2)(C)). Applicants request for the PTA to be corrected.

B. Terminal Disclaimer

The above-identified application is not subject to a Terminal Disclaimer.

C. Reasonable Efforts

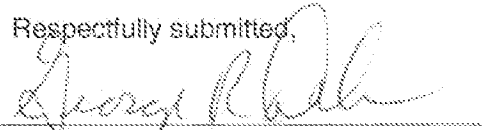
Any applicant delays under 37 C.F.R. §1.704 are set forth above. There were no other circumstances constituting a failure to engage in reasonable efforts to conclude processing of examination of the above-identified application, as set forth in 37 C.F.R. §1.704.

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Date:

10/20/09

Respectfully submitted,



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